caBIG Workspace Adopter Project Form

Adopters, please complete this form in advance of the caBIG kickoff meeting and return by e-mail to adamsm@mail.nih.gov. Completed forms will be made available to participants in advance of the meeting to enhance workspace discussions. During our conversations with you, we expressed the aspect of your program that we would like you to develop in the first year of the caBIG pilot; it is this we are asking you to address - here and in your presentation.

1. Sponsoring Cancer Center: **Duke Comprehensive Cancer Center**

2. Workspace: **Clinical Trials Management**

3. What "data" are you providing as adopters?

Access to Breast SPORE Phase II clinical trial data: past accrual and real-time accrual
- **Data types: clinical, laboratory, radiology, tissue collection and imaging, genomic/ microarray**

Extended to other clinical trial activity:
- **Breast SPORE**
- **Program Project Grant**
- **Cancer Center Clinical Trials Shared Resource**

4. What are the tools you envision would enhance the use and analysis of this "data"?

- **Electronic administrative management tool**
- **Electronic data management tool**
- **Electronic data entry interface**
- **Web-based application**
- **Report writing tools**
- **Dataset output: SAS, S-Plus, Excel**
- **Site specific access for remote data collection site: web portals**

5. What is your ability to evaluate the tools to be adopted?

Systematic feedback mechanism
Designated adoptor team:
- **Clinical workflow: principal investigator, clinical research assistants and other clinical staff**
- **Data workflow: data entry, data manager and other database staff**

6. How will you provide system integration?

Cancer Center Information Systems is committed to conform to established and chosen caBIG standards

Ability to use most platforms

7. How will you provide end-user testing?

Data Manager and Programmers will interact to provide
- **workflow testing**
- **interface testing**

- **data validity testing**

8. How will you provide software validation?

Functional requirements and expectations will be determined and periodically examined during the course of implementation

Assessment by data manager, programmers, statisticians and clinicians at the end of the pilot

9. What are your plans for interacting with the appropriate workspace developers?

Develop a web-based project workspace application, tightly linked to the development of the clinical-genomic data infrastructure,that will allow project collaborators to access relevant data and contribute new information and results of analyses to other members of the collaborative team. We will pilot this in a SPORE funded breast cancer clinical trial. This workspace will be critical for facilitating the work of a multi-disciplinary team of investigators, providing the opportunity to carry on analyses in a simultaneous fashion. This will also be a mechanism to link together groups of investigators at other cancer centers who are collaborating in clinical-genomic based projects.

- **Year 1 – initial development and implementation**
- **Years 2,3 – enhancement and extension to inter-cancer center use**